UNITED STATES DEPARTMENT OF AGRICULTURE

DEPUTY ADMINISTRATOR
STAKEHOLDER MEETING WITH
REPRESENTATIVES OF THE
WEYERHAEUSER COMPANY

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DEPUTY ADMINISTRATOR)
STAKEHOLDER MEETING WITH)
REPRESENTATIVES OF THE)
WEYERHAEUSER COMPANY)

Room 6B01CN U.S. Department of Agriculture 4700 River Road Riverdale, Maryland

Thursday, October 20, 2005

The parties met, pursuant to notice, at 1:00 p.m.

PARTICIPANTS:

For the Weyerhaeuser Company:

BOB EMORY Weyerhaeuser Company 1785 Weyerhaeuser Road Vanceboro, North Carolina 28586 (252) 633-7417

ANDREA HOWELL

Federal Government Affairs Manager 1100 Connecticut Avenue, N.W., Suite 530 Washington, D.C. 20036-4118 (202) 293-7222

PETER FARNUM, Vice President Forestry and Raw Materials Research 32901 Weyerhaeuser Way South P.O. Box 9777 Federal Way, Washington 98063-9777

APPEARANCES: (Cont'd.)

For the Agency:

THOMAS CLINT NESBITT
MIKE WACH
REBECCA STANKIEWICZ GABEL
JOHN TURNER
JOHN CORDTS
SALLY McCAMMON
LEVIS HANDLEY
USDA-APHIS-BRS
4700 River Road
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- 2 (1:00 p.m.)
- 3 MR. NESBITT: Okay. So I would like to
- 4 thank our guests for joining us here this afternoon
- 5 and participating in our monthly stakeholder meeting
- 6 days. We typically like to give our stakeholders the
- 7 opportunity to come in and give formal input on the
- 8 record about our regulatory policies.
- 9 We're primarily interested at this point in
- 10 getting feedback on our programmatic environmental
- 11 impact statement that we're developing and the
- 12 subsequent future rule revisions.
- In the interest of openness, I should say
- 14 that we are obviously recording this meeting. We'll
- 15 be producing an official transcript that we'll post on
- 16 the Web, along with a list of the people's names who
- 17 are attending. So it follows from that that you
- 18 should please not discuss any confidential business
- 19 information in this meeting, because it will be made
- 20 public.
- Our meetings typically last about 45
- 22 minutes, which is free for you to use however you
- 23 wish, but I should point out that this is a listening
- 24 session, so it's primarily up to you to give us input,
- 25 however you wish to use the time.

- I think probably the best way to begin maybe
- 2 we'll go around the room and introduce ourselves and
- 3 our sort of roles within APHIS Biotechnology
- 4 Regulatory Services, and then we'll let you introduce
- 5 yourselves and take over from there.
- 6 You want to start?
- 7 MR. WACH: Okay. I'm Mike Wach and I'm --
- FEMALE VOICE: That's my branch chief.
- 9 MR. WACH: Regulatory Analyst, Regulatory
- 10 Analysis Branch, and it's my job to actually shepherd
- 11 the EIS through the regulatory process, and I'm also
- 12 helping facilitate the drafting of the new rules.
- 13 MR. NESBITT: And my name is Clint Nesbitt.
- 14 I'm a AAAS Fellow here in BRS, and my responsibility
- 15 here is largely to manage these meetings.
- 16 MS. STANKIEWICZ GABEL: I'm Rebecca
- 17 Stankiewicz Gabel, and I'm a regulatory analyst in the
- 18 Regulatory Analysis Branch, and I'm also responsible
- 19 for public input for EIS and rules and that type of
- 20 thing.
- 21 MR. HANDLEY: And I'm Lee Handley. I'm a
- 22 senior biotechnologist in the Plants Branch of the
- 23 Risk Assessment Group.
- 24 MR. CORDTS: I'm John Cordts, and I'm also a
- 25 senior biotechnologist in the Plants Branch of the

- 1 Environmental Risk Analysis Division.
- 2 MR. TURNER: I'm John Turner. I'm director
- 3 of the Policy Coordination Division, which has
- 4 Regulatory Analysis. It has our International Group
- 5 and Communications and Capacity Building.
- 6 MS. McCAMMON: And I'm Sally McCammon. I'm
- 7 a science advisor. I head our Office of Science, and
- 8 my primary responsibility is to make sure what we do
- 9 is science-based.
- 10 MS. HOWELL: Well, I guess I'll get started.
- 11 I'm Andrea Howell with Weyerhaeuser. I'm a Federal
- 12 Affairs Manager, and I just want to thank you for
- 13 taking the opportunity to visit with us and providing
- 14 this opportunity for the stakeholder meetings.
- 15 We're going to have -- Bob Emory is going to
- 16 talk about Weyerhaeuser and talk about -- give you a
- 17 little bit of background about the company, and then
- 18 Peter Farnum will follow up with a lot more details
- 19 about our research and development program and our
- 20 thoughts and comments on some of the scoping questions
- 21 you had asked related to the programmatic EIS.
- So, with that, Bob.
- 23 MR. EMORY: Okay. Do I need to move this
- 24 microphone? Okay. As Andrea said, I'm Bob Emory.
- 25 I'm the Environmental Manager for our southern

- 1 timberlands operations, and I want to just take just a
- 2 few minutes to provide some information about
- 3 Weyerhaeuser which will help set the context for what
- 4 Dr. Farnum will then follow up with.
- 5 We appreciate the opportunity to be here to
- 6 comment on the proposed changes to the regulations,
- 7 and we support revising those regulations.
- 8 Weyerhaeuser is a company of 53,000
- 9 employees in 19 countries. Ninety-five percent of our
- 10 employees are in the U.S. and in Canada. And the
- 11 safety of our employees and our contractors is
- 12 paramount for us, and we have as a goal to reduce the
- 13 rate of recordable safety incidents to one per 100
- 14 employees per year, which is a very low incident rate,
- 15 and we're well on the way to that goal.
- We manufacture hundreds of products that
- 17 people use every day. We're a global leader in a
- 18 number of product lines, including softwood and
- 19 hardwood lumber, engineered lumber, softwood market
- 20 pulp, container board packaging, and uncoated free
- 21 sheet paper.
- We -- around the world, we own or manage 38
- 23 million acres of forest land, and in North America,
- 24 we're one of the largest forest landowners, and we
- 25 have 6.8 million acres right here in the United States.

- 1 We rank 89th in Fortune magazine's 2005
- 2 ranking of the largest corporations in America. Our
- 3 goal is to have Weyerhaeuser be synonymous with
- 4 responsible, science-based forest management, and in
- 5 the U.S. over the last 50 years, we've increased the
- 6 productivity of our lands between 200 and 300 percent.
- 7 This has required long-term investments, but as a
- 8 company that's over a century old, we have a long-term
- 9 perspective.
- 10 We believe that the improved productivity on
- 11 our lands and those of others who use similar
- 12 practices will help the world meet its demands for
- 13 wood fiber and free up other lands for less intensive
- 14 management or to meet other societal needs.
- That productivity gain has been the result
- 16 of a considerable investment in research and
- 17 development, and we feel like we are without peer in
- 18 our commitment to forestry R&D, and you'll hear more
- 19 about that program later in this testimony.
- We've achieved third-party certification of
- 21 forestry practices in environmental management systems
- 22 on all of our managed forest lands. Our approach to
- 23 certification relies on two types of standards.
- The first addresses management systems and
- 25 processes that you need to have to meet environmental

- 1 goals and to manage and mitigate the impacts of our
- 2 operations, and for that, we've adopted ISO 14001,
- 3 which is a globally recognized standard, and all of
- 4 our forest lands have been certified to ISO 14001.
- 5 The second type of standard focuses on the
- 6 actual practices that are associated with growing and
- 7 harvesting trees, such as protecting streams,
- 8 protecting wildlife habitat, preventing erosion, and
- 9 in the U.S., we have selected the Sustainable Forestry
- 10 Initiative standard to cover that part of our
- 11 operation.
- 12 This year marks the 25th anniversary of an
- 13 event that shaped Weyerhaeuser's culture for decades
- 14 to come, and that was the eruption of Mount St. Helens
- in southwestern Washington state.
- 16 Following that eruption, with single-minded
- 17 determination, we salvaged enough timber to build
- 18 85,000 three-bedroom homes. We then faced the problem
- 19 of how to reforest that land, some of which had as
- 20 much as three feet of volcanic ash on it.
- 21 Our research scientists and our foresters
- 22 developed the techniques that allowed us to do that,
- 23 and as a result, we planted over 18 million seedlings
- 24 on 45,000 acres, and this year, we're thinning that
- 25 forest that we established after Mount St. Helens'

- 1 eruption.
- 2 And to commemorate the return of that
- 3 forest, we've pledged a million dollars in materials
- 4 and money, along with employee volunteers, to build 32
- 5 Habitat homes across the U.S., across North America.
- 6 And we're still planting trees, 100 million in five
- 7 countries during the past year.
- Biotechnology may well be the leap forward,
- 9 the next leap forward in forest productivity, an
- 10 advance that again will allow the world to meet its
- 11 need for wood fiber on fewer acres.
- 12 If you were to go to a Home Depot or Lowe's
- 13 Building Supply Center, you would discover that the
- 14 market for forest products is global. You might find
- 15 lumber from Finland or Sweden, and increasingly around
- 16 the world pulp and paper products are coming from the
- 17 southern hemisphere, where they enjoy in many cases a
- 18 better climate and lower labor costs and they operate
- 19 in a different regulatory environment than we do.
- 20 With paper coming from the southern
- 21 hemisphere under those conditions, it affects the cost
- 22 structure of the paper industry, and that's something
- 23 that we're having to react to. It's putting a lot of
- 24 pressure on the paper industry in the U.S.
- 25 So how can U.S. firms remain competitive

- 1 with internal produced -- with international producers
- 2 given those conditions?
- We view biotechnology as an important
- 4 opportunity that we're vitally interested in, and
- 5 we're interested in biotechnology regulation being
- 6 both predictable and based on scientific principles.
- 7 Pete.
- 8 MR. FARNUM: Thanks. I'm Peter Farnum. I
- 9 am Vice-President of Timberlands Technology, but in
- 10 the talk, I'll just refer to forestry research as it's
- 11 easier.
- 12 Our forestry research got started in 1940
- 13 and it's been continuous ever since and has grown a
- 14 lot. We now have 120 people working in forestry
- 15 research, 50 of whom are scientists.
- 16 Our center is in -- near our corporate
- 17 headquarters in Federal Way, Washington and -- but we
- 18 have scientists located at field research centers
- 19 around the country, eight different places.
- 20 Currently our single largest area of
- 21 research is tree genetics based on classical breeding
- 22 techniques. I can give you an example of that. Our
- 23 tree breeding in the south started in 1955, and
- 24 because of that early start, we're now entering a
- 25 fourth generation of breeding and testing and

- 1 selection on some of our most advanced regions.
- We have a big program. We have 1500 parents
- 3 ourselves and several thousand other parents are being
- 4 tested by cooperators. On our own lands, we've
- 5 completed 700 genetic trials and we've tested about
- 6 1.3 million trees.
- We also have a program in biotechnology.
- 8 That program is focused very tightly on vegetative
- 9 propagation using somatic embryogenesis, and what we
- 10 propagate are the highest value trees from our
- 11 classical breeding program.
- 12 Weyerhaeuser does not do any internal
- 13 research on transgenes. We do belong to a couple of
- 14 university co-ops that do.
- The thing that distinguishes I think
- 16 Weyerhaeuser's research, forestry research most is the
- 17 size and the nature of our environmental research.
- 18 We have scientists who specialize in
- 19 wildlife sciences, aquatic biology, geology,
- 20 hydrology, and plant ecology, and in fact, a quarter
- 21 of our research investment is directed -- is in the
- 22 environmental area and it's directed towards
- 23 understanding the environmental impact of our
- 24 practices and to identify ways to improve those
- 25 practices.

- 1 I should point out that none of
- 2 Weyerhaeuser's environmental research is proprietary,
- 3 and as an aside, I can say the part of our genetics
- 4 research that has to do with adaptability or
- 5 environmental impacts, none of that's proprietary
- 6 either.
- 7 In the environmental area, there's two
- 8 products. One is better practices, and the other is
- 9 coauthored papers and peer reviewed journals, which
- 10 are usually used or often used by regulators at all
- 11 levels.
- 12 In the environmental area, we take an
- 13 ecosystem-wide perspective looking at risks and
- 14 benefits, and it's designed to work in an adaptive
- 15 management process.
- We look at a practice. If it's efficacious
- 17 and there are minimal or beneficial environmental
- 18 impacts, then we'll continue.
- 19 That isn't always the case. Sometimes we
- 20 look at environmental -- at a forestry practice and we
- 21 find improvements need to be made, and so we'll adjust
- 22 our management accordingly.
- 23 So our process is one of continual
- 24 improvement, improvement that's based on sound and
- 25 transparent scientific data since none of it's

- 1 proprietary and most of it's published.
- I want to tell you about our research
- 3 approach and how we think about research, because when
- 4 I get to the specific comments on the questions you
- 5 ask, it'll I think be more in context if you
- 6 understand how we think about science.
- We of course in our research program explore
- 8 new technology, and if the technologies look
- 9 promising, then they're evaluated for practicality,
- 10 they're evaluated for economic payback and the company
- 11 may then decide to go ahead and implement that
- 12 technology.
- But it's really important that we don't stop
- 14 our research at that time. When we've decided to
- 15 implement a technology, we put in new research studies
- in the first operational stands where that technology
- 17 has been implemented.
- 18 And why do we do that? Because whatever's
- 19 going to happen with that technology, whether it's
- 20 going to work like we want it to or whether there are
- 21 going to be surprises, it'll happen first on our
- 22 research plots and those are the most closely watched
- 23 parts of our forest.
- So that gives us a way to identify changes
- 25 we need to make in a timely manner. We can make

- 1 proactive changes, and that's obviously tied in with
- 2 our active management process. And we think that
- 3 approach has promise for genetic engineering
- 4 applications as well.
- Weyerhaeuser's approach to science is very
- 6 data-oriented. We have a heavy reliance on empirical
- 7 results with a broad inference base. All our studies
- 8 are designed to represent the land base that we own.
- 9 We try very hard internally to avoid the use
- 10 of expert opinion, but we can't always do that because
- 11 sometimes to make quick business decisions, the
- 12 businesspeople will say give us the best answer you
- 13 can and give it to us now.
- But when we do that, if it leads to an
- 15 important decision, we put in followup studies,
- 16 because the experts had a hypothesis and that
- 17 hypothesis needs to be tested.
- 18 So Weyerhaeuser believes that as the
- 19 regulation of transgenes moves forward, there should
- 20 be more and more emphasis on databased results and
- 21 less and less emphasis on expert opinion.
- 22 If I quote the National Academy of Sciences
- 23 1989 report, they said, "The necessity exists for
- 24 timely field research of genetically modified plants
- 25 in environments similar to those where they will be

- 1 used". That's the end of their quote.
- 2 We think very strongly that same necessity
- 3 for empirical research exists today, especially with
- 4 regard to environmental impacts.
- 5 As Bob said, we support your efforts to
- 6 improve the Biotechnology Regulatory Services program.
- 7 We think to date, the program for regulation of GMOs
- 8 has been successful in the sense that both the economy
- 9 and the society have benefitted from their use without
- 10 apparent significant impact to people or the
- 11 environment, and we hope that any changes being
- 12 considered should have the goal of improving on the
- 13 success you've had already.
- 14 In order to base your regulation of GMO tree
- 15 crops on sound science, we'd encourage you to
- 16 understand forestry practices, forestry ecology, and
- 17 forest genetics, both the practical breeding as well
- 18 as the evolutionary aspects, and we think APHIS should
- 19 encourage research on genetically engineered trees and
- 20 use those results.
- 21 So we -- it's -- I'm trying to make it
- 22 obvious. We support the need to conduct studies and
- 23 gather data, and we're willing to participate with
- 24 others in genetic or ecological impact studies and
- 25 we're willing to share our over 50 years of experience

- 1 in research and development.
- I want to give you an example of our
- 3 science-based implementation because again it
- 4 underlies -- it has parallels in genetic engineering
- 5 and it will help explain some of my later answers.
- In the early '80's, we adopted the practice
- 7 of planting loblolly pine that was developed in our
- 8 classical tree improvement program in North Carolina,
- 9 where we would take the seed from our seed orchards
- 10 there, move it to Arkansas and Oklahoma, grow
- 11 seedlings in Arkansas and Oklahoma and plant them
- 12 there.
- This is an example of how we assess and
- 14 manage risk, because we identified from our early
- 15 research tests the opportunity for a 20 percent rate
- 16 of growth. That's what the research tests showed.
- 17 But there was a significant drought in 1980,
- 18 and we noticed that the North Carolina source had a
- 19 higher rate of mortality.
- 20 So before we implemented, we solicited
- 21 external review from prominent scientists. We
- 22 published the results of our thinking, and then we
- 23 made the operational decision to go ahead.
- But when we decided to proceed, in order to
- 25 reduce the risk, we only planted the North Carolina

- 1 material on the deepest soils with the highest water
- 2 holding capacity, and like I said before, we also
- 3 started an internal research program so we could
- 4 understand the risks, understand why they were
- 5 occurring, and we think the risk we face might fall
- 6 into the category that you call minor unresolved risk.
- 7 So it's important to note that we deployed
- 8 with a plan to mitigate those risks and with a
- 9 research program to understand them better.
- In addition to the research, we established
- 11 a monitoring program which was statistically designed
- 12 that each fall we would do a disciplined helicopter
- 13 survey of stands made up of the local source versus
- 14 stands made up of the North Carolina source to
- 15 understand the differential survival.
- 16 And over the years, after the results of the
- 17 monitoring and the research came in, those results
- 18 supported our original conclusion that the benefits of
- 19 growing the North Carolina source on our lands in
- 20 Arkansas and Oklahoma exceeded the risk of drought
- 21 mortality.
- 22 But we didn't stop managing risk there. We
- 23 bred a hybrid between the two sources, and that hybrid
- 24 has the best traits of each of the providences and has
- 25 well adapted to the local environment, so that further

- 1 reduces risk.
- 2 I think it's important that this forest
- 3 resource -- and this covers I'm not sure, over a
- 4 million acres I believe -- this forest resource
- 5 provides an opportunity for research, because some of
- 6 the plantations are now more than 25 years old, and
- 7 Weyerhaeuser manages trees at wider spacings than most
- 8 other companies. So the pines there in these 25-year
- 9 old stands have large crowns and are producing seed
- 10 and pollen obviously.
- 11 Now we don't know the actual molecular basis
- 12 of the rapid growth, but certainly it's due to
- 13 genetics, and we think this provides the opportunity
- 14 to understand and progression rates of new alleles
- 15 into natural stands where both inter- and
- 16 intraspecific hybridization may be occurring.
- 17 It's also an opportunity to look at whether
- 18 there's been any weediness developed. If you move a
- 19 trait of 20 percent faster growth, does that create a
- 20 weediness issue?
- 21 We think this example is relevant to APHIS
- 22 because it involves a genetic change to a very
- 23 familiar trait, perhaps the most familiar trait, which
- 24 is faster plantation growth.
- I should say on a related issue, as we look

- 1 from the outside, we think the developers of GMO trees
- 2 are in a kind of catch-22 when trying to develop hard
- 3 scientific data on intragression and hybridization
- 4 because of course their studies have to be terminated
- 5 before flowering.
- 6 So we'd encourage you to allow the
- 7 scientific community the regulatory leeway to design
- 8 studies for trees let's say having a reporter gene or
- 9 other probable fitness-neutral or fitness-reducing
- 10 transgene.
- 11 We believe these genes are generally
- 12 accepted as being benign when released on a small
- 13 scale. Given that, the trees could be allowed to
- 14 flower in designed studies and we would be able to
- 15 study directly some of the important questions that
- 16 need to be answered.
- 17 There's an even more difficult problem which
- 18 you know about which is we need methods to study the
- 19 effects of transgenes that are not fitness-neutral.
- Okay. Now let me get to responding to your
- 21 questions in the January 23rd Federal Register. The
- 22 first question is you said you're interested in
- 23 broadening your regulatory scope to include
- 24 genetically engineered plants that may pose a noxious
- 25 weed risk, and we think that's a good idea.

- 1 Weediness is very definitely an
- 2 environmental issue and it can be studied, although
- 3 you know as well as our -- as well as we do that
- 4 studying weediness is difficult, but with the kind of
- 5 adaptive management that I talked about and very
- 6 intensive monitoring and early identification and
- 7 perhaps using the study or resource that I talked
- 8 about before, it would be possible to do that.
- 9 And again, I point out in the case of our
- 10 seed source movement, we did concurrent monitoring and
- 11 research and we had defined expectations and we think
- 12 those are the best way to approach this potential
- 13 risk, the risk of weediness and forestry with
- 14 monitoring, research, and having clear expectations.
- In all our own genetic research from
- 16 classical breeding, we have not experienced any
- 17 reports or complaints of weediness.
- 18 Now having said that and having preached the
- 19 need for data, we don't have any data on that because
- 20 we haven't constructed any specific studies, but we
- 21 manage a lot of traits in our classical program, and
- 22 the effects of those traits, the potential weediness
- 23 could be studied using our genetic program and we'd
- 24 certainly be open to cooperative efforts with
- 25 universities or other stakeholders to look into that.

- 1 Another question or another area you talk
- 2 about is considering revisions to regulations that
- 3 would define specific risk categories, and at the end
- 4 of that section, you ask: Should certain low-risk
- 5 categories be considered for exempting from permitting
- 6 requirements?
- 7 If you do move to the categorical approach,
- 8 we think it should be based on the criteria in the
- 9 decision trees from the 1989 National Academy of
- 10 Sciences report, and those of course were familiarity
- 11 with the species and trait and evaluation of the
- 12 potential environmental risk, and the way I think
- 13 about it, if you take familiarity and evaluation of
- 14 potential environmental risk, you can get four
- 15 categories.
- 16 You can get high familiarity-low
- 17 environmental risk, high familiarity-high
- 18 environmental risk, low familiarity-low environmental
- 19 risk, and low familiarity and high environmental risk.
- 20 So that's an alterative way to think about a
- 21 categorical approach, and I'll use that construct in
- 22 some later comments. I should say that the
- 23 case-by-case approach that you've used to date seems
- 24 to have worked well and should not be discarded
- 25 quickly.

- 1 Weyerhaeuser believes that trees should not
- 2 be treated differently from other plant species.
- 3 Certainly the timeframes are longer, but we think the
- 4 scientific principles are the same, and longer time
- 5 periods in fact may permit relatively earlier
- 6 identification of potential problems.
- 7 For example, doing research on weediness, if
- 8 it started at the time of deployment and there's a
- 9 careful monitoring program, that could lead to
- 10 adaptive management practices which would prevent
- 11 problems.
- 12 Your second question about whether certain
- 13 low-risk categories should be exempted from
- 14 permitting, we would say yes, and we would say the
- 15 cases that fall into the high familiarity-low
- 16 environmental risk categories could be exempted.
- 17 What's an example of that or some criteria
- 18 for that? Well, for instance, a genetically
- 19 engineered trait should be exempted if it's
- 20 essentially similar to that which has been produced or
- 21 could be produced in two or three generations of
- 22 classical breeding, and essentially similar is the
- 23 term that the National Academy of Sciences used.
- 24 And again, they talk about testing in
- 25 environments like they're going to be used. The --

- 1 those same traits are being worked on in the classical
- 2 engineering program and already being managed in those
- 3 environments.
- 4 I would define classical breeding to include
- 5 intra- and interspecific hybrids of native species and
- 6 trees produced through vegetative propagation.
- 7 So if a group of native genes occurring
- 8 naturally in a species where hybridization occurs,
- 9 that group of genes confers a phenotype, which is
- 10 similar to a trait that a transgene construct
- 11 produces, then we think that should be categorized as
- 12 high familiarity-low environmental risk.
- 13 An example might be a transgene that affects
- 14 wood properties by modifying biochemical function in
- 15 the same way as naturally occurring genes.
- Some traits that might fall into the high
- 17 familiarity-low environmental risk category would
- 18 include growth rate under plantation management,
- 19 changes in the relative amounts of chemicals that
- 20 already exist in the wood, for instance, reduced
- 21 ligna, and changes in wood structure, such as less
- 22 juvenile wood.
- 23 The point I want to make is that our
- 24 industrial research programs, the classical research
- 25 programs are already managing those traits and trees

- 1 like that are already being planted out and so they
- 2 should be familiar traits, and I've already discussed
- 3 how we could do research to see whether there were any
- 4 environmental effects.
- If you were to go this way, an exemption
- 6 process could include general permitting such as the
- 7 general storm water permits managed by EPA. Under
- 8 this system, you would define a set of criteria or
- 9 best management practices required as conditions for
- 10 deployment or commercialization.
- 11 The next question asked about allowing for
- 12 commercialization of certain genetically engineered
- 13 organisms while continuing in some cases to regulate
- 14 the organism based on minor unresolved risks, and we
- 15 think the flexibility to do that is a good idea.
- We think the example that I gave of moving
- 17 the North Carolina seed to Arkansas and Oklahoma dealt
- 18 with a minor unresolved risk. There's going to be
- 19 many cases where not all the information that's wanted
- 20 is in, but the evidence we have suggests a low risk
- 21 that shouldn't slow down commercialization.
- 22 So, in these cases, we think it's reasonable
- 23 to commercialize while at the same time conducting
- 24 concurrent scientific studies and monitoring.
- 25 We think APHIS should establish clear

- 1 criteria to identify cases with low risk of
- 2 undesirable environmental effects, and this is another
- 3 area where you might use a regulatory structure of
- 4 general permitting or other BMP process.
- 5 I want to point out that this situation of
- 6 implementing a technology while at the same time still
- 7 having some unresolved risk is a very common one in
- 8 forestry.
- 9 Our forestry research or industry research
- 10 organization, the National Council of Air and Stream
- 11 Improvement, in fact has been doing research in
- 12 situations like these for 27 years, and I can give you
- 13 just two quick examples of that.
- One is pine plantations in wetlands. There
- 15 were concerns about what they would do to wetland
- 16 functions. There were concerns about impacts on
- 17 estuaries. And NCASI spent millions and millions of
- 18 dollars of research and it showed little, if any,
- 19 disruption to wetland functions, and as a result, no
- 20 permitting was required under the Clean Water Act, and
- 21 all this was done during commercialization.
- It always doesn't turn out quite that
- 23 cleanly. NCASI and we have done impact -- have done
- 24 studies on the BMPs for road building and the effect
- on water quality, and when we've done those studies,

- 1 we found out that the BMPs had to be changed. They
- 2 had to be improved.
- For example, it used to be that the ditches
- 4 on the sides of the roads could drain directly into
- 5 streams and they carry a large sediment load. That
- 6 obviously wasn't good for water quality. And now the
- 7 BMPs require that the ditches be disconnected from the
- 8 streams, that they be diverted, the water be diverted
- 9 into the forest where erosion and water quality will
- 10 not be a problem.
- 11 Another area where targeted research could
- 12 be done contemporaneously with commercialization is
- 13 for GMO traits which might otherwise be classified as
- 14 high risk but are deployed with flower control, such
- 15 that outcrossing cannot meaningfully occur. In this
- 16 case, the unresolved risk is the efficacy of flower
- 17 control for the full length of the rotation.
- 18 You could address this by allowing that
- 19 study to go forward, monitoring whether there were
- 20 flowers or there was pollen, whether there was seed
- 21 produced, and providing for requirements from
- 22 mitigation if monitoring identified unacceptable
- 23 levels of risk.
- There's other unresolved risks having to do
- 25 with flower control, such as the effect on wildlife,

- 1 which is highly seed-dependent in the diet. For
- 2 instance, the brown-headed nuthatch, which is -- lives
- 3 in the south and a lot of our forests has 56 percent
- 4 of its diet of pine seeds.
- 5 But we could conduct studies of wildlife
- 6 populations near stands with flower control and
- 7 wildlife studies near wild stands and compare them and
- 8 see what the impact was, or the risk could be
- 9 mitigated right from the start by planting a mixture
- 10 of flower-controlled GMO trees with fertile,
- 11 classically bred trees at a landscape level, and using
- 12 techniques as these, the risks could be understood and
- 13 could be rendered very low.
- 14 And in fact, I mentioned landscape level.
- 15 Many minor risks can likely be managed at the
- 16 landscape level because of the diversities in the
- 17 landscape that exists in our forests.
- 18 We think the key to managing low levels of
- 19 risk during deployment is a well-defined process with
- 20 clear criteria agreed upon prior to commercialization,
- 21 and there needs to be a process to end regulatory
- 22 oversight if the data indicate an acceptably low risk
- 23 as well as a parallel process to increase controls if
- 24 the data goes the other way.
- 25 You asked about nonviable plant material.

- 1 We think it should not be regulated other than for its
- 2 own toxicity to the environment.
- 3 We think in forestry, the most nonviable
- 4 plant material would likely be the logging residue,
- 5 the branches, the bark, et cetera that we leave on the
- 6 site to maintain soil productivity.
- 7 But in cases like the ones I've been talking
- 8 about where the trait itself is nontoxic, it seems
- 9 highly unlikely that the logging residue would be
- 10 toxic. So if it's a high familiarity-low risk case,
- 11 then the nonviable plant material wouldn't need to be
- 12 regulated.
- And much the same logic exists for another
- 14 question about adventitious presence. If you're
- 15 dealing with a trait that's high familiarity-low
- 16 environmental risk, then it seems there wouldn't be
- 17 additional need for regulation of adventitious
- 18 presence.
- 19 On the other hand, if you're dealing with a
- 20 case where there minor unresolved risks, then
- 21 commercialization would seemingly only be able to go
- 22 forward if accompanied by a research and monitoring
- 23 program.
- So I'll just conclude saying Weyerhaeuser
- 25 supports your efforts to improve the Biotechnology

- 1 Regulatory Services program, and we think with sound
- 2 science driving the regulation of GMO trees,
- 3 commercialization could commence for many applications
- 4 when the technology has been sufficiently developed.
- 5 Those cases would include those which fall
- 6 into the high familiarity-low environmental risk
- 7 category. They also could include those with minor
- 8 unresolved risks if commercialization were accompanied
- 9 by concurrent monitoring and research.
- 10 So we think your program has been successful
- 11 and we're confident that any changes you make to
- 12 current policy will build on that foundation and it
- 13 will make America even more competitive and keep our
- 14 nation at the forefront of technological advances in
- 15 global forestry.
- MR. NESBITT: Very good. Thank you very
- 17 much for your presentation. I may at this point ask
- 18 if there are others here who would like to ask
- 19 questions or perhaps points of clarification.
- John, do you have anything you would like
- 21 to revisit?
- 22 MR. TURNER: No. It was a fascinating
- 23 presentation. We got a lot of experience with row
- 24 crops, maybe not as much with trees, but we're
- 25 certainly aware that that doesn't make them high risk,

- 1 that the biology of trees is well known in many cases
- 2 and the biology of the genes may be well known, so
- 3 we're going to bear that in mind as we go forward and
- 4 see many of these products coming up closer to
- 5 fruition.
- I'm not sure I had too much more, but I
- 7 think the idea of doing some basic research with
- 8 marker genes, with neutral genes or even what's known
- 9 as domestication genes and negative fitness genes is
- 10 something we would really support too.
- We're not in any direct sense a research
- 12 funding agency and we certainly can cooperate to do
- 13 research, but I think it's -- there's a need there,
- 14 and that would do a lot for the regulators if we had
- 15 more of that type of data, so I was very encouraged to
- 16 hear you also recognize that need.
- 17 MR. FARNUM: We think that's one
- 18 contribution we can make. With a strong research
- 19 background, we should continually urge the industry
- 20 and the government to promote research like that so we
- 21 do have hard scientific data.
- MR. WACH: Peter, you mentioned this
- 23 interplay between expert opinion and empirical data.
- MR. FARNUM: Right.
- MR. WACH: And I'm wondering if you see

- 1 either in our regulations or in the way we implement
- 2 our regulations that same interplay. I have a feeling
- 3 you brought that up for a reason, and I want to know
- 4 if you feel that there is something in our -- you
- 5 know, either in our regulations themselves or in how
- 6 we implement them where we rely on expert opinion as
- 7 opposed to relying on empirical data.
- 8 MR. FARNUM: I brought it up because I read
- 9 the testimony that people have given you and that
- 10 you've published on the Web.
- MR. WACH: I see.
- MR. FARNUM: And it seemed a lot of that
- 13 fell into people exhorting their expert opinion.
- 14 MR. WACH: Well, I'm glad you said that.
- 15 MR. FARNUM: And I have a particular hot
- 16 button about it, so I brought it up for that reason,
- 17 not because of any critique of what you've been doing.
- 18 MR. WACH: Okay. Good. I'm glad I got that
- 19 clear.
- 20 MR. FARNUM: That was not meant at all to be
- 21 critical.
- 22 MR. WACH: Okay. No. It wasn't so much
- 23 critical as it might be an observation that we don't
- 24 ourselves see, so that -- it's fine.
- 25 MR. TURNER: All depends on which expert you

- 1 ask.
- 2 MALE VOICE: That's right.
- 3 MR. FARNUM: Isn't that the truth.
- 4 MR. NESBITT: Mike, is there any other
- 5 questions you want to --
- 6 MR. WACH: That was -- I think that was --
- 7 oh. You mentioned about and you came up with a
- 8 specific number. Whenever I hear a specific number,
- 9 I'm going to have to ask about it.
- 10 You mentioned in the context of high
- 11 familiarity-low risk items, you said something that
- 12 could be achieved in two to three generations of
- 13 classical breeding, and I'm -- is that really that
- 14 predictable?
- 15 Could I mention a trait to you like a --
- 16 something that you'd want in a tree and you could tell
- 17 me well, that'll take about, you know, two, three,
- 18 four, five generations? Can you actually pin it down
- 19 like that?
- 20 MR. FARNUM: We can make estimates based on
- 21 genetic theory, based on the various -- variance
- 22 components of -- which we get from our genetic tests,
- 23 and you can project what future generations will give
- 24 from analyzing those genetic components and using some
- 25 Mendelian theory. So yes, but you have to have good

- 1 data on -- from your tests on the variance components.
- MR. WACH: So this would probably be a trait
- 3 that either already existed in a tree so you knew that
- 4 there was some variability in the tree?
- 5 MR. FARNUM: Right.
- 6 MR. WACH: It couldn't be a novel trait? It
- 7 would have to be something that pretty much already
- 8 existed in the species or within the genus that you're
- 9 working with?
- 10 MR. FARNUM: Yes. Actually, that's a good
- 11 point. Everything I said fall -- was really about
- 12 those kinds of traits.
- MR. WACH: Okay.
- MR. FARNUM: Traits -- because --
- MS. McCAMMON: We're talking at the
- 16 phenotypic level.
- 17 MR. FARNUM: At the phenotypic level,
- 18 because those would be the familiar traits.
- MR. WACH: Okay.
- MR. NESBITT: Anyone else at the table have
- 21 any other questions or points of clarification that
- 22 you'd like to raise?
- MR. HANDLEY: You mentioned that in the
- 24 United States, you're growing under the SFI standard
- 25 for growing and harvesting, and in other parts of the

- 1 world, are you working under different standards or
- 2 are you working under different certifications in
- 3 different countries?
- 4 MR. EMORY: We work under the national
- 5 standard for whatever country we were operating, if
- 6 there is one.
- 7 MR. HANDLEY: Okay.
- 8 MR. EMORY: And if there isn't one, we're
- 9 working toward helping develop one.
- 10 MR. HANDLEY: Okay. Do you -- have you
- 11 operated under the Forest Stewardship Council
- 12 standards at all?
- MR. EMORY: We bought MacMillan Bloedel, and
- 14 they had I believe a small part of their ownership
- 15 perhaps in Canada that was under FSC certification.
- 16 That has been the extent of it.
- 17 MR. HANDLEY: Okay. Thanks.
- 18 MS. McCAMMON: I just had a couple comments
- 19 just to follow up on something John had said, this
- 20 idea of doing some of the research with the markers
- 21 and neutral genes, but also the research on the
- 22 weediness would be really helpful for us, and I think
- 23 to have that trait as to how that impacts particularly
- 24 the trees that are being developed now.
- The other question is a little bit of an

- 1 open-ended question that I have is you had mentioned
- 2 having a predictable regulatory system and you've kind
- 3 of given some ideas of processes that you thought
- 4 would be helpful. Did you have any other comments to
- 5 make on what that would entail for you?
- 6 MR. EMORY: The predictability is just a
- 7 trait of regulation that we always like to see.
- MS. McCAMMON: Uh-huh.
- 9 MR. EMORY: Specific traits where
- 10 predictability would be more important than others
- 11 I'll punt that over to Pete.
- 12 MR. FARNUM: I -- because forestry is such a
- 13 long-term business and forestry research is such -- so
- 14 long-term, if the regulatory environment is uncertain,
- 15 it provides a strong disincentive for us to get
- 16 involved in that area, so we're always hoping for more
- 17 certainty.
- 18 MR. NESBITT: Okay. Are there any other
- 19 questions on this side? Do the three of you have any
- 20 other comments you'd like to close with?
- MR. EMORY: None from me.
- 22 MR. FARNUM: Do you have examples of what
- 23 you consider minor unresolved risks? I just took a
- 24 quess at that.
- MR. NESBITT: I guess that would be for Mike.

- 1 MR. TURNER: I think when we hold the
- 2 stakeholder meetings, we're probably asked that
- 3 question more than any other, and I'm not going to
- 4 answer it now either.
- 5 We don't really. Right now when we
- 6 deregulate a product, deregulate means exactly what it
- 7 sounds like literally. It's no longer under
- 8 regulation, so we've often been asked but you could
- 9 put conditions, you could put stipulations if you
- 10 wanted to, if you needed some monitoring data, and now
- 11 we can't. And I think we haven't had the need to any
- 12 great extent, but as a new generation of products come
- 13 along, there may be the need.
- 14 Certainly the idea of trees has come along,
- 15 you know, in the discussion, not to pick on trees or
- 16 nothing's decisional even whether we will go to that
- 17 option only because of the long lifespan.
- 18 Maybe it would take a long time to get the
- 19 same type of data you would get from something else,
- 20 but that doesn't mean that we've decided to do without
- 21 municipal trees or not.
- 22 But we saw it not as an extra burden now we
- 23 deregulate and if we did this, we might deregulate --
- 24 we might allow it to go to commercial but have
- 25 restrictions, but as a way to let some things move

- 1 forward before they have met the same burden if the
- 2 risks were minor and there were ways to mitigate the
- 3 risk. So specific examples, I can't really give that.
- 4 MR. FARNUM: Okay.
- 5 MR. TURNER: Maybe trees, maybe not. But --
- 6 and also really you have to see the product. When the
- 7 petition lands here and you get into the specifics,
- 8 that's when those sort of things really come out.
- 9 Maybe there would be, you know, unsolved minor risks,
- 10 but certainly, you know, if there were major, we
- 11 couldn't let it go forward.
- MR. FARNUM: Sure.
- 13 MR. TURNER: And it's been difficult to say
- 14 exactly what we mean by minor unresolved risk except
- 15 to say that it would be something that was acceptable
- 16 and something that could be mitigated.
- 17 MS. McCAMMON: I wanted to know that an
- 18 Academy Report took an additional tack in that, you
- 19 know, you may have some solid answers at a certain
- 20 scale for a particular issue like weediness or gene
- 21 flow, but that you're not as certain at very large
- 22 scales, you know, with millions of acres, and so they
- 23 had suggested, whether it be by regulation or not,
- 24 that there be this followup monitoring to verify and
- 25 validate that the assumptions and conclusions from the

- 1 original assessment were correct.
- 2 MR. FARNUM: In the case of our moving the
- 3 North Carolina to Arkansas, our -- at the beginning,
- 4 our upper estimate of mortality was one percent per
- 5 year extra mortality, which would certainly have
- 6 negated a lot of the 20 percent gain.
- 7 After we did all the monitoring and
- 8 research, it turned out to be something on the order
- 9 of a quarter percent per year. So it was -- it did in
- 10 fact turn out to be minor and something which didn't
- 11 negate the benefit.
- MR. NESBITT: Very good. Well, I think
- 13 we're coming close to the end of our allotted time, so
- 14 with that, I would like to thank our guests who are
- 15 here from Weyerhaeuser on behalf of APHIS
- 16 Biotechnology Regulatory Services, and thank you again
- 17 for coming.
- 18 MR. EMORY: Thank you.
- 19 MR. FARNUM: Thank you for having us.
- 20 (Whereupon, at 1:51 p.m., the hearing in the
- 21 above-entitled matter was adjourned.)
- 22 //
- 23 //
- 24 //
- 25 //

REPORTER'S CERTIFICATE

CASE TITLE: Deputy Administrator Stakeholder

Meeting With Representatives of the

Weyerhaeuser Company.

HEARING DATE: October 20, 2005

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the meeting in the above before the United States Department of Agriculture.

Date: October 20, 2005

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